REMARKS

Applicant respectfully requests reconsideration.

Claims 13, 164 and 485-520 were previously pending in this application. Claims 513 and 514 are cancelled.

Claims 13, 164, 497-500, 511 and 512 are amended. Support for these amendments can be found in the specification at least at page 2 lines 7-8, page 4 lines 27-29, page 11 lines 24-25 and 29-30, page 32 line 12, page 78 lines 27-29 and page 85 lines 27-33, and in previously pending claims 513 and 514.

As a result, claims 13, 164, 485-512 and 515-520 are pending for examination with claims 13 and 164 being independent claims. Claims 485-500, 507 and 508 are currently withdrawn. Claims 497-500 are amended to provide structures for the claimed compounds. Rejoinder of these claims is requested as a result. Consideration of the remaining withdrawn claims is also requested once the currently examined species are found allowable. No new matter has been added.

Applicant requests clarification of the Examiner's comments on page 2 of the Office Action relating to an influenza antigen present in a bacteria. Applicant reiterates the election of a subject exposed to an influenza antigen. Nothing in this election refers to bacteria. Applicant requests that the Examiner clarify the comment.

Rejection under 35 U.S.C. §101

Claims 164, 502, 504, 510, 512, 514, 516, 518 and 520 are rejected under 35 U.S.C. §101 because, according to the Examiner, "the claimed invention is allegedly not supported by a well established utility". The Examiner particularly objects to the recitation of "preventing an infectious disease" as recited in claim 164, since he considers this to mean "that not a single virus, bacteria, fungus, parasite or prion can divide or propagate or replicate while present within the subject".

Applicant respectfully points out that "preventing", as it relates to subjects at risk of developing a disorder, is defined in the specification, on pages 78-79, as " ... a decrease in the probability that the subject will develop the disorder ... ". Thus the term is not defined as

stringently as the Examiner proposes. The Examiner must interpret the claims based on the definitions provided in the specification.

The claimed invention therefore meets the USPTO utility guidelines in the field of biotechnology, namely, "(having) a specific, substantial and credible utility". The rejected claims relate to the use of a *specific* genus of compounds for a *specific* purpose (i.e., preventing an infectious disease, as defined in the specification). Prevention of infectious disease is a *substantial* utility. The prior art is replete with agents that prevent infectious disease (including vaccine and immunoglobulin therapies) and therefore the claims also embrace a *credible* utility.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, first paragraph

Enablement

Claims 164, 502, 504, 506, 510, 512, 514, 516, 518 and 520 are rejected under 35 U.S.C. §112, first paragraph. The Examiner states that "since the claimed invention is not supported by a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention". Based on the definition of prevention as defined in the specification, Applicant maintains that these claims define a specific, substantial and credible utility, and they are therefore enabled by the specification in view of the state of the art at the time of filing.

Reconsideration and withdrawal of the rejection is respectfully requested.

Written Description

Claims 511-512 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such way as to reasonably convey to one of ordinary skill in the relevant art that the applicant, at the time the application was filed, had possession of the claimed invention.

The Examiner states that there is no support for the "96%" limitation. Applicant draws the Examiner's attention to page 4 lines 27-29 and page 32 line 12 of the specification, and claim 369 as originally filed, which recite the "96%" limitation.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, second paragraph

Claim 13, 164, 501-506 and 509-520 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 164 are rejected because of the recitation of "agent". Claims 13 and 164 involve administering an "agent" of Formula I. The term was used and understood in the art at the time of filing. For example, Stedman's Medical Dictionary defines agent as an active force or substance capable of producing an effect. Applicant intended an "agent" to be synonymous with a "compound" having the structure recited in the rejected claims.

Claims 13 and 164 are rejected because the claims do not recite a carrier. Claims 13 and 164 are amended to include the limitation of "a pharmaceutically acceptable carrier". Support for these amendments can be found in the specification at least on page 85 lines 27-30.

Claims 13 and 164 are rejected because of the recitation of "to inhibit the infectious disease" because, according to the Examiner, "disease" itself is not a process and hence cannot be "inhibited". Claims 13 and 164 are amended to recite "an effective amount to inhibit the progression of an infectious disease". Support for these amendments can be found in the specification at least on page 78 lines 27-29.

Claims 13 and 164 are rejected because of the recitation of infectious disease. Applicant respectfully points out that the term "infectious disease" is defined in the specification at least on page 12 lines 7-11, and various examples of infectious disease are also provided at least on pages 12 and 13.

Claims 13 and 164 are rejected because of the recitation of "R can be" and "A may be". Claims 13 and 164 are amended to recite "R is" and "A is".

Claims 13 and 164 are rejected because of the recitation of "A_m". Claims 13 and 164 are amended to recite "Am" where m denotes the number of "A".

Claims 13 and 164 are rejected because of the definition of A_1. Claims 13 and 164 are amended to recite "amino acid residue". Support for these amendments can be found in the claims themselves and in the specification at least on page 2 lines 18-20 where A is defined as an

amino acid residue. One of ordinary skill in the art would understand the meaning of A_1 in the formula.

Claims 13 and 164 are amended to include a comma between "fluoroolefins" and "dipeptide isoesteres".

Claims 13 and 164 are rejected because of the recitation of "alphaketos". The term refers to alphaketo containing reactive moieties such as alphaketo amides, alphaketo esters, and alphaketo acids, all of which were known in the art prior to the filing date as evidenced by U.S. Patent No. 5965532. The term is therefore clear. Notwithstanding this, Applicant has amended claims 13 and 164 to recite "alphaketo moiety".

Claims 13 and 164 are rejected because of the recitation of FAP. The specification on page 41 lines 27-28 teaches that FAP is a cell surface marker of reactive stromal fibroblasts, and the claims state that FAP is a post-prolyl cleaving enzyme. At the time of filing, the term was recognized in the art as referring to "fibroblast activation protein" (see for example, U.S. Patent Nos. 5587299, 5767242 and 5965373), each of which describes FAP or FAPα as present in reactive stromal fibroblasts and/or as related to DPP-IV, an art-recognized post-prolyl cleaving enzyme. Therefore, one of ordinary skill in the art would recognize and understand the term in the context of the present disclosure.

Claims 13 and 164 are amended to correct a typographical error and recite "N-peptidyl-O-acylhydroxylamine".

Claims 13 and 164 are rejected because of the recitation of "it is capable of reacting". Claims 13 and 164 are amended to recite "R reacts".

Claims 511-512 are rejected because the claims contemplate a mixture but the independent claims from which they depend, are drawn to a single agent. Claims 13 and 164 are amended to recite "a composition comprising an agent of Formula I". The composition therefore can comprise a single agent or a mixture of agents. Applicant draws the Examiner's attention to page 32 lines 12-13 of the specification, which states that the chiral center at issue is the carbon bonded to the reactive group, such as boron. Thus, the 96% limitation in the claims means that 96% of the agents in the mixture have a carbon atom bound to the reactive group (e.g., boron) in an L-configuration.

In view of the foregoing, the terms and claims are considered definite and reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Priestly

Claims 13, 164, 503-506 and 509-520 are rejected under 35 U.S.C. §103 as being obvious and unpatentable over Priestley (U.S. Pat. 6939854). Applicant respectfully traverses.

According to the Examiner, the cited reference discloses peptides having the formula "Asp-Glu-Val-Xaa-W wherein Xaa is an amino acid such as ethylglycine or tbutyl-phenethylglycine, and W is a substituent variable used in the reference, and represents boronic acid pinanediol ester". The Examiner cites Table 1 as support for this teaching. Applicant is unable to find such a structure in Table 1. Instead, Table 1 teaches peptides of the minimal formula of H-Asp-Glu-Val-Val-Xaa_1-Xaa_2-W, where W is as stated by the Examiner, Xaa_2 can be 2-(4-tertbutyl phenyl)ethyl, and notably Xaa_1 is proline or O-Bzl substituted proline. Accordingly, the "isoleucine" position is occupied by proline or a proline derivative and not a valine as asserted by the Examiner. The Examiner's position that it would be obvious to a peptide chemist of ordinary skill to extend an amino acid side chain by one methylene unit without loss of activity is therefore not relevant.

The Examiner has cited *In re Shetty* and *In re Hass & Susie* in support of his position that structural similarities render obviousness. Applicant notes that in *In re Shetty* there existed prior art that referred to the compounds at issue as *homologs*. No such teaching has been put forth by the Examiner in the instant case. Applicant maintains that substitution of the proline for isoleucine is not an obvious modification, at least because these amino acids are not homologs of each other. Applicant also respectfully points out that the holdings in the cited cases are now "cautioned" or even considered "questionable", and therefore it is doubtful that they represent the current state of the law and/or should be relied upon by the Examiner.

Reconsideration and withdrawal of this rejection is respectfully requested.

Wallner

Claims 13 and 164 are rejected under 35 U.S.C. §103 in view of Wallner (U.S. Pat. 6355614). Claims 13 and 164 are amended to recite that the subject is HIV negative. Wallner teaches treatment of subjects in need of hematopoietic (including lymphoid) stimulation and proliferation. Wallner teaches treatment of subjects having HIV because this condition is "characterized by inadequate lymphocyte activation or concentration". (See col 12 lines 20-29.) Wallner does not teach treatment of subjects having an infectious disease other than HIV. Treatment of non-HIV infectious diseases would not be obvious at least because they are not commonly associated with below normal hematopoietic (including lymphoid) cell numbers. Claim 164 relates to the prevention of infectious disease and therefore includes the limitation of treating a subject at risk of developing an infectious disease but not a subject already having such a condition. Wallner does not explicitly contemplate prevention of HIV, presumably because a subject not yet infected with HIV has normal hematopoietic cell numbers. Thus, claims 13 and 164 as amended are not rendered obvious by Wallner.

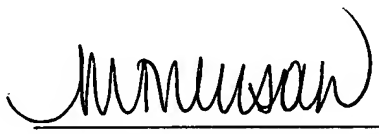
Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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